SCANNED

UNDERSEAL

FILED
OCT 12 2010
RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA AND THE STATE OF CALIFORNIA, *ex. rel.* [UNDER SEAL], **Plaintiff/Relator,** **vs.** **[UNDER SEAL],** **Defendants.**	**CIVIL ACTION NO.:** CV 10 4597 **COMPLAINT** **FILED IN CAMERA AND UNDER SEAL**

BZ

Barbara Giuffre (California SBN: 158180)
Richard W. Raushenbush (California SBN: 134983)
WORK/ENVIRONMENT LAW GROUP
351 California Street, Suite 700
San Francisco, CA 94104
Telephone: (415) 981-9114
Facsimile: (415) 434-0513
Barbara@igc.org
Richard@workenvirolaw.com

Attorneys for Relator Manuel Alcaine

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA and the STATE OF CALIFORNIA, *ex rel.* MANUEL ALCAINE,

Plaintiff/Relator,

vs.

BRADEN PARTNERS, LP, doing business as PACIFIC PULMONARY SERVICES, TEIJIN-PHARMA USA LLC, doing business as PACIFIC PULMONARY SERVICES, PETER B. KELLY and CHAD HEATH MARTIN, individuals and as general partners of BRADEN PARTNERS, LP; SAN LEANDRO SLEEP DISORDERS CENTER, P.C.; CONTRA COSTA SLEEP CENTER, LLC; DR. KIRIT PATEL, DR. JAGJEET KALRA and DR. RON KASS doing business as HAYWARD EB SLEEP DISORDERS CENTER; DR. MAN KONG LEUNG doing business as PACIFIC COAST SLEEP DISORDERS and DR. HARAMANDEEP SINGH doing business as SLEEP MEDICINE SPECIALISTS OF CALIFORNIA,

Defendants.

Civil Action No. *******

Complaint for Violations of Federal False Claims Act and California False Claims Act

FILED UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)

DO NOT PLACE IN PRESS BOX

DO NOT PLACE ON PACER

JURY TRIAL DEMANDED

Relator Manuel Alcaine, through his attorneys Work/Environment Law Group, on behalf of the United States of America and the State of California, for his Complaint against defendants: Braden Partners, LP doing business as Pacific Pulmonary Services ("PPS"), Teijin-Pharma USA LLC also doing business as PPS, and Peter B. Kelly and Chad Heath Martin as general partners of Braden Partners, LP; the San Leandro Sleep Disorders Center, P.C.; the Contra Costa Sleep Center, L.L.C.; Dr. Kirit Patel, Dr. Jagjeet Kalra and Dr. Ron Kass doing business as the Hayward EB Sleep Disorders Center; Dr. Man Kong Leung doing business as Pacific Coast Sleep Disorders; and Dr. Haramandeep Singh doing business as Sleep Medicine Specialists of California, alleges based upon personal knowledge and relevant documents, as follows:

I. INTRODUCTION

1. This is an action to recover treble damages and civil penalties on behalf of the United States of America and the State of California arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendants and/or their agents, employees and co-conspirators to the Federal Medicare, Medicaid, and TRICARE programs (collectively, "federal health care programs") in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 *et seq.*, as amended ("the FCA" or "the Act"), and to the California Medi-Cal program in violation of the California False Claims Act, Cal. Government Code §12650 *et seq.* (the "Cal-FCA" or "California Act").

2. To enhance their profits at the expense of taxpayer-funded government health care programs, Defendants caused many false and/or fraudulent claims to be made on federal and California health care programs. The conduct at issue includes the following:

a. In violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), Defendant PPS knowingly provided Defendants San Leandro Sleep Disorders Center, P.C., Contra Costa Sleep Center, L.L.C., Hayward EB Sleep Disorders Center, Pacific Coast Sleep Disorders, and Sleep Medicine Specialists of California (among other sleep testing facilities) (the "Sleep Test Defendants") with, and such Defendants knowingly solicited and received, the illegal remuneration of patient referrals for sleep testing paid for by federal and California health care programs to induce such Defendants, and the physicians affiliated therewith, to prescribe PPS sleep therapy equipment and service paid for by federal and California health care programs. Such conduct violated PPS' express certification in its Medicare Enrollment Application for DMEPOS Suppliers, CMS Form 855S, that it would "abide by the Medicare laws, regulations and program instructions" applicable to it as a condition of payment (the "PPS Medicare Certification"), and rendered its claims for Medicare payment false and fraudulent. Such conduct also violated PPS' express certification in its Medi-Cal Provider Agreement, DHCS Form 6208, that it would "comply with all federal laws and regulations governing and regulating Medicaid providers" (the "PPS Medi-Cal Certification"), and rendered its claims for Medi-Cal and Medicaid payment false and fraudulent.

b. In violation of the Anti-Kickback Statute, the Sleep Test Defendants (among other sleep testing facilities) knowingly provided PPS with, and PPS knowingly solicited and received, the illegal remuneration of patient prescriptions for PPS sleep therapy equipment and service paid for by federal and California health care programs to induce PPS to refer patients to such Defendants for sleep testing paid for by federal and California health care programs. Such conduct violated the Sleep Test Defendants' express certifications in their Medicare Enrollment Application: Physicians and Non-Physician Practicioners, Form CMS-855I or Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers, Form CMS-855B, that each would "abide by the Medicare laws, regulations and program instructions" applicable to it as a condition of payment (the "Sleep Test Defendants Medicare Certifications"), and rendered their claims for Medicare payment false and fraudulent. Such conduct also violated the Sleep Test Defendants' express certification in their Medi-Cal Provider Agreement, DHCS Form 6208, that each would "comply with all federal laws and regulations governing and regulating Medicaid providers" (the "Sleep Test Defendants Medi-Cal Certifications"), and rendered their claims for Medi-Cal and Medicaid payment false and fraudulent.

c. PPS knowingly submitted false "At-Rest" pulse oximetry testing results to qualify patients to receive PPS oxygen equipment and service paid for by federal and California health care programs.

d. In violation of the Anti-Kickback Statute, PPS knowingly provided physicians with the illegal remuneration of free use of PPS pulse oximeters in exchange for and to induce such physicians to prescribe and sign Certificates of Medical Necessity ("CMNs") for PPS oxygen equipment and service paid for by federal and California health care programs. Such conduct constituted an illegal kickback, violated the PPS Medicare Certification and rendered its claims for

Medicare payment false and fraudulent. Such conduct also violated the PPS Medi-Cal Certification, and rendered its claims for Medi-Cal and Medicaid payment false and fraudulent.

e. PPS, a DME supplier, knowingly violated Medicare rules and corrupted the integrity of the tests by performing pulse oximetry tests on Medicare patients. Physicians then relied upon the DME supplier's own tests to prescribe and sign CMNs for PPS oxygen equipment and services paid for by federal health care programs. Such conduct violated the PPS Medicare Certification and rendered its claims for Medicare payment false and fraudulent.

f. PPS knowingly violated Medicare program instructions limiting DME supplier involvement in overnight home pulse oximetry testing. Contrary to the rules, PPS selected the Independent Diagnostic Testing Facility ("IDTF") that received the test results, accessed data before forwarding it to the IDTF, and instructed and showed patients how to use the oximetry equipment – none of which PPS, a self-interested DME supplier, is permitted to do. PPS knew that physicians relied upon the overnight pulse oximetry results to prescribe and sign CMNs for PPS oxygen equipment and services paid for by federal health care programs. Such conduct violated the PPS Medicare Certification and rendered its claims for Medicare payment false and fraudulent.

g. PPS knowingly violated Medicare rules that limit DME supplier marketing to Medicare patients. Contrary to the rules, PPS contacted patients in physician waiting rooms, hospitals, clinics and during home visits (when delivering sleep therapy equipment), and attempted to convince patients that they should have pulse oximetry testing for oxygen services and equipment or enhanced oxygen services and equipment. PPS also knowingly violated Medicare rules by recommending pulse oximetry testing of patients to physicians at their offices, at hospitals and in clinics. Such solicitations led to physicians prescribing and signing CMNs for PPS oxygen equipment paid for by federal health care programs. Such conduct violated the PPS Medicare Certification and rendered its claims for Medicare payment false and fraudulent.

h. PPS knowingly violated Medicare rules limiting DME supplier involvement in completing CMNs signed by physicians for PPS oxygen equipment and services paid for by federal health care programs. Such conduct violated the PPS Medicare Certification and rendered its claims for Medicare payment false and fraudulent.

3. Under the False Claims Act, a private person may, under some circumstances, bring an action in federal district court for himself and for the United States, and may share in any recovery. 31 U.S.C. § 3730(b). That private person is known as a "relator," and the action that the relator brings is called a *qui tam* action. Similarly, under the California False Claims Act, a private person, known as the *qui tam* plaintiff, may, under some circumstances, bring an action on behalf of the State of California and share in the recovery. California Government Code § 12652(c)(1), (g)(2). Alcaine is a Relator.

4. This Complaint initiates a *qui tam* action brought by Relator Alcaine on behalf of the United States and the State of California.

5. As required by the False Claims Act, 31 U.S.C. § 3730(b)(2), Relator has provided to the Attorney General of the United States and to the United States Attorney for the

Northern District of California a statement of substantially all material evidence and information related to this Complaint. As required by the California False Claims Act, California Government Code § 12652(c)(3), Alcaine has served the same statement by mail with return receipt requested upon the California Attorney General. This disclosure statement is supported by material evidence known to Relator at the time of this filing establishing the existence of Defendants' false claims. Because the statement includes attorney-client communications and work product of Relator's attorneys, and is submitted to the Attorneys General and to the United States Attorney in their capacity as potential co-counsel in the litigation, the Relator understands this disclosure to be privileged and confidential.

II. PARTIES

6. Relator Manuel Alcaine ("Alcaine" or "Relator") is a resident of the State of California. He was employed by PPS from March 2, 2009 through January 27, 2010 (the "relevant period"). He is the original source of the facts and information set forth in this Complaint concerning the activities of PPS and the Sleep Test Defendants. The facts alleged herein are based upon his personal observation and upon documents and information in his possession.

7. Defendant Braden Partners, LP is a limited partnership formed in California in 1990. Its principal place of business is 88 Rowland Way, Suite 300, Novato, CA 94945.

8. In 2006, Defendant Braden Partners, LP registered to transact business in the State of Florida as a foreign limited partnership, identifying its principal place of business as 88 Rowland Way, Suite 300, Novato, CA 94945. Since 2006, Braden Partners, LP has filed Annual Reports with the Florida Secretary of State.

9. At all times relevant hereto, Defendants Peter B. Kelly and Chad H. Martin were general partners in Braden Partners, LP.

10. Teijin Limited, a Japanese company, is the holding company for the Teijin Group, another Japanese company. According to the Teijin 2009 Annual Report: "In June 2008, we acquired a controlling interest in Braden Partners LP, a leading U.S. provider of respiratory devices for home health care."

11. Defendant Teijin-Pharma USA LLC is a limited liability corporation incorporated in the State of Delaware in August 2008. Its members, as of September 2008, were President and Chief Executive Officer Peter B. Kelly, Vice-President and Chief Financial Officer Chad Heath Martin, Chief Operating Officer Chris M. Kane, Chief Alliance Officer Jun Koyama, and Secretary, Treasurer and Chief Governance Officer Kazuo Imose, each with their business address at 88 Rowland Way, Suite 300, Novato, CA 94945.

12. Defendant Teijin-Pharma USA LLC applied for authorization to transact business in Florida in September 2008. The Teijin-Pharma USA LLC application was filed on Pacific Pulmonary Services letterhead showing a business address of 88 Rowland Way, Suite 300, Novato, CA 94945, and asked that correspondence be directed to Scott Hertzberg of Braden Partners, L.P. at 88 Rowland Way, Suite 300, Novato, CA 94945.

13. Braden Partners, LP does business both in its own name and as Pacific Pulmonary Services in California and a number of other states. As an employee of PPS, Alcaine received paychecks from Braden Partners, LP. The January 2009 PPS Employee Handbook states that Braden Partners, LP does business as Pacific Pulmonary Services.

14. In the County of Alameda, California, where many of the acts described in this Complaint occurred, Braden Partners, LP registered as the owner of the fictitious business name Pacific Pulmonary Services from 2003 through 2006, with the final expiration date of the

registration being July 19, 2011. On October 9, 2008, Teijin-Pharma USA LLC registered as the owner of the fictitious business name Pacific Pulmonary Services in Alameda County.

15. In the County of Contra Costa, California, where many of the acts described in this Complaint occurred, Braden Partners, L.P. registered as the owner of the fictitious business name Pacific Pulmonary Services on in 2004 and 2006. Braden Management Corporation registered as the owner of the fictitious business name Pacific Pulmonary Services on April 28, 2008. On October 9, 2008, Teijin-Pharma USA LLC registered as the owner of the fictitious business name Pacific Pulmonary Services in the County of Contra Costa, California.

16. Based upon the foregoing business filings and compensation provided to employees of PPS, Relator alleges that both Defendant Braden Partners, LP and Defendant Teijin-Pharma USA LLC are doing business in California as Pacific Pulmonary Services.

17. Defendants Braden Partners, LP doing business as PPS, Teijin-Pharma USA LLC also doing business as PPS, and Peter B. Kelly and Chad Heath Martin as general partners of Braden Partners, LP, are referred to herein as the "PPS Defendants." Each of the PPS Defendants is jointly and severally liable for the conduct of PPS set forth herein.

18. Defendant San Leandro Sleep Disorders Center is a professional corporation incorporated in California in 2006. Its principal place of business is 13939 E. 14th St., Suite 180, San Leandro, CA 94578. SLSDC is owned, in whole or in part, by Dr. R.S. Rajah, Dr. B. Roberston, Dr. Paul Robinson, Dr. N. Abudayeh, Dr. K. Rothman, Dr. Robert Wu, Dr. A Jian, Dr. D. Dhawan, Dr. Ronald Rubenstein, Dr. Christi Cheng, Dr. Douglas Zhang, Dr. Dariush Zandi, Dr. A. Massen and Dr. V. Sawney.

19. Defendant Contra Costa Sleep Center, L.L.C. is a limited liability company registered in California with its principal place of business at 1700 Ygnacio Valley Blvd., Suite 100, Walnut Creek, CA 94598.

20. Defendant Hayward EB Sleep Disorders Center is a sleep test business operated by Dr. Kirit Patel, Dr. Jagjeet Kalra and Dr. Ron Kass with its principal place of business located at 27001 Calaroga Ave., Suite 1, Hayward, CA 94545.

21. Defendant Pacific Coast Sleep Disorders is a sleep test business operated by Dr. Man Kong Leung with its principal place of business at 4466 Black Avenue, Suite A, Pleasanton, CA 94566.

22. Defendant Sleep Medicine Specialists of California is a fictitious business name for a sleep test business owned by Dr. Haramandeep Singh. Its principal place of business at 5201 Norris Canyon Road, Suite 120, San Ramon, CA 94583.

III. JURISDICTION AND VENUE

23. Jurisdiction is based on 28 U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. In addition, 31 U.S.C. §3732(b) specifically confers jurisdiction on this Court over the state law claims asserted in this Complaint.

24. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the defendants have minimum contacts with the United States. Moreover, the Defendants can be found in, reside, or transact or have transacted business in this district.

25. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because the Defendants can be found in and transact or have transacted business in this district. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this

district, maintained employees and offices in this district, and made significant sales within this district. In addition, statutory violations, as alleged herein, occurred in this district.

IV. OVERVIEW OF APPLICABLE LAW

A. Federal False Claims Act

26. The False Claims Act, 31 U.S.C. §§ 3729-33, addresses fraud in the provision of supplies and services to the United States government. Section 3729 of the FCA provides, in pertinent part, that:

> [(a)(1)] Subject to paragraph (2), any person who—
>
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of subparagraph (A), (B) [or] (G);
>
> . . .
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410 [1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.

25. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

B. Federal Anti-Kickback Statute

27. The federal health care Anti-Kickback Statute ("AKS"), 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary or directed to a supplier of more products that are more expensive than necessary. To protect the integrity of federal health care programs from these harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

28. The AKS prohibits any person or entity from paying or accepting remuneration to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b(b).

29. With respect to paying kickbacks, Congress provided in 42 U.S.C. §1320a-7b(b)(2):

> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

30. Under this statute, DME suppliers may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend DME equipment or services that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any provision of "free," but valuable, services that has as one of its purposes inducement of a physician to write prescriptions for the supplier's DME products and services.

31. Similarly, under the AKS, physicians or clinics providing sleep testing services may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce a DME supplier or others to recommend that such physicians or clinics perform sleep testing that may be paid for by a federal health care program.

32. With respect to soliciting or receiving kickbacks, Congress provided in 42 U.S.C. §1320a-7b(b)(1):

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

33. Under this prong of the AKS, DME suppliers may not knowingly and willfully solicit or receive any remuneration, including prescriptions for sleep therapy equipment and services, directly or indirectly, in return for referring patients or recommending that physicians refer patients to physicians or clinics to perform sleep testing that may be paid for by a federal health care program.

34. Similarly, under the AKS, physicians or clinics providing sleep testing services may not solicit or receive any remuneration, including patient referrals or recommendations to refer patients, directly or indirectly, in return for prescribing a DME supplier's sleep therapy equipment and services that may be paid for by a federal health care program.

35. Violation of the Anti-Kickback statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§ 1320a-7b; 1320a-7a.

C. The Medicare Program

36. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain health care services. Entitlement to Medicare

is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426, 426A. Part A of the Medicare Program authorizes payment for institutional care, including hospital, skilled nursing facility, and home health care. *See* 42 U.S.C. §§ 1395c-1395i-4. Part B of the Medicare program authorizes payment for outpatient health care expenses, laboratory services, durable medical equipment and physician fees, among other things. *See* 42 U.S.C. §§ 1395j-1395w-4.

37. Defendants derived revenue from the Medicare program during the relevant period.

38. The U.S. Department of Health and Human Services ("HHS") is responsible for the administration and supervision of the Medicare program. The Center for Medicare and Medicaid Services ("CMS"), an agency of HHS, is directly responsible for the administration of the Medicare program. CMS selected four companies to process durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") claims to the Medicare program. These companies are called Durable Medical Equipment Medicare Administrative Contractors ("DME MACs"). During the relevant period and to the present, Noridian Administrative Services is the DME MAC for a jurisdiction that includes the entire State of California.

39. Under the Medicare program, sleep therapy devices, including continuous positive airway pressure ("CPAP") devices and bi-level positive airway pressure ("BiPAP") devices (together, "PAP devices"), and related supplies are considered durable medical equipment ("DME). Similarly, home oxygen equipment and related supplies are considered DME under the Medicare program.

40. For a DME supplier to file a claim for payment for PAP devices and supplies under the Medicare program, the equipment and supplies must have been authorized by a

physician through a prescription. For a DME supplier to file a claim for payment for home oxygen equipment and supplies under the Medicare program, the equipment and supplies must have been authorized by a physician through a Certificate of Medical Necessity (CMN).

41. The Medicare program will only pay for DME that meets the appropriate medical necessity standards (e.g., ordered, provided, reasonable, necessary, and meeting criteria established by medical review policies).

42. To supply DME to Medicare patients and be paid by the Medicare program, a DME supplier must submit and sign a CMS-855S, the MediCare Enrollment Application for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers. Submitting the Application and signing the Certification Statement therein is a prerequisite to participating in the Medicare program and receiving payment from the Medicare program.

43. The Application requires certification that: "My signature legally and financially binds this supplier to the laws, regulations, and program instructions of the Medicare program." Further, Section 15: Certification Statement provides: "These are additional requirements that the supplier must meet and maintain to bill the Medicare program. Read these requirements carefully. By signing, the supplier is attesting to having read the requirements and understanding them. ... You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below. ... I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback

statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare." (Emphasis added). The signatory, on behalf of the applicant, also promises: "If I become aware that any information in this application is not true, correct, or complete, I agree to notify the NSC of this fact immediately."

44. During the relevant period, as a supplier of oxygen equipment, oxygen, PAP devices and related supplies to Medicare patients, PPS was enrolled as a Medicare DMEPOS supplier. It made the certification set forth in the preceding paragraph (the "PPS Medicare Certification").

45. Under the Medicare program, to qualify for coverage of PAP devices, the patient must undergo a Medicare-covered sleep test. "A Medicare-covered sleep test must be either a polysomnogram performed in a facility-based laboratory (Type I study) or a home sleep test (HST) (Types II, III, or IV). The test must be ordered by the beneficiary's treating physician and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements." Noridian, LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L171).

46. Under the Medicare program, an entity qualified to perform a polysomnogram ("PSG") may be either an individual physician or a clinic/group practice. To perform sleep tests and be paid by the Medicare program, an individual physician must submit a Medicare Enrollment Application: Physicians and Non-Physician Practioners, Form CMS-855I, and a clinic/group practice must submit Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers, Form CMS-855B.

47. Form CMS-855B requires signature by an authorized signatory for the sleep test supplier and requires certification that: "My signature legally and financially binds this supplier

to the laws, regulations, and program instructions of the Medicare program." The signatory also agrees, on behalf of the applicant, that "If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare fee-for-service contractor of this fact immediately." Section 15: Certification Statement provides: "These are additional requirements that the supplier must meet and maintain to bill the Medicare program. Read these requirements carefully. By signing, the supplier is attesting to having read the requirements and understanding them. ... You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below. ... I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare." (Emphasis added).

48. Form CMS-855I requires signature by the individual physician and certifies that the physician is "meeting and maintaining the Medicare requirements" in the Certification Statement. The physician certifies: "I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in Section 4A of this application. The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law),

and on the supplier's compliance with all applicable conditions of participation in Medicare." (Emphasis added). The physician further agrees: "If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare fee-for-service contractor of this fact immediately."

49. During the relevant period, as suppliers of sleep testing to Medicare patients, the Sleep Test Defendants were enrolled as Medicare clinics/group practices or as individual physicians and made the either the Certification in Form CMS 855B or Form CMS-855I set forth in the preceding paragraphs (the "Sleep Test Defendants Medicare Certification").

D. California False Claims Act

50. The California False Claims Act, California Government Code §§ 12650-12656, is similar to the FCA and serves the same purpose. Section 12651(a) provides:

> 12651. (a) Any person who commits any of the following enumerated acts in this subdivision shall have violated this article and shall be liable to the state or to the political subdivision for three times the amount of damages that the state or political subdivision sustains because of the act of that person. A person who commits any of the following enumerated acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and shall be liable to the state or political subdivision for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000) for each violation:
>
> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.

(2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim.

(3) Conspires to commit a violation of this subdivision.

...

(7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state or to any political subdivision, or knowingly conceals or knowingly and improperly avoids, or decreases an obligation to pay or transmit money or property to the state or to any political subdivision.

51. Under Section 12652(c)(1), a "person may bring a civil action for a violation of this article for the person and ... for the State of California in the name of the state, if any state funds are involved."

E. The Medi-Cal Program

52. Medi-Cal is California's Medicaid program and, under the provisions of Title 22 of the California Code of Regulations, the Department of Health Care Services ("DHCS") administers the program. DHCS has statutory responsibility to formulate policy that conforms to Federal and State requirements. California has contracted with a Fiscal Intermediary (FI), HP Enterprise Services, to receive and process Medi-Cal claims.

53. Medi-Cal is a public assistance program providing for payment of medical expenses for the poor and disabled, who may or may not also qualify for help from Medicare. Medi-Cal is financed equally by California and the United States. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding,

which is called federal financial participation. 42 U.S.C. §§1396 et seq. Medi-Cal helps pay for medically necessary services by a physician and other things, including DME.

54. To supply oxygen, oxygen-related equipment, PAP devices or PAP-related suppliers to Medi-Cal patients and be paid by the Medi-Cal program, a DME "provider" must complete a Medi-Cal Provider Agreement, DHCS Form 6208. An authorized signatory for the provider must attest, among other things: "Provider agrees to comply with all applicable provisions of Chapters 7 and 8 of the Welfare and Institutions Code (commencing with Sections 14000 and 14200), and any applicable rules or regulations promulgated by DHCS pursuant to these Chapters. … Provider further agrees to comply with all federal laws and regulations governing and regulating Medicaid providers. Provider agrees that it shall not engage in or commit fraud or abuse. "Fraud" means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or herself or some other person. It includes any act that constitutes fraud under applicable federal or state law." (Emphasis added). In signing the Provider Agreement, the provider agrees "that compliance with the provisions of this agreement is a condition precedent to payment to provider." (Emphasis added).

55. The foregoing Certification includes agreement to comply with the federal Anti-Kickback Statute as one of the "federal laws and regulations governing and regulating Medicaid providers." *See, e.g.,* 42 U.S.C. § 1320a–7b(f).

56. During the relevant period, as a supplier of oxygen, oxygen-related equipment, PAP devices and PAP-related supplies to Medi-Cal patients, PPS applied for enrollment as a Medi-Cal DME supplier, submitted the Provider Agreement and made the Certification set forth in the preceding paragraph (the "PPS Medi-Cal Certification").

57. During the relevant period, PPS derived revenue from the Medi-Cal program.

58. To supply sleep test services to Medi-Cal patients and be paid by the Medi-Cal program, a provider of sleep test services also must submit a Medi-Cal Provider Agreement, DHCS Form 6208, and make the certification therein.

59. During the relevant period, as suppliers of sleep testing to Medi-Cal patients, the Sleep Test Defendants were enrolled as Medi-Cal providers and made the Certification in DHCS Form 6208 set forth in the paragraph above (the "Sleep Test Defendants Medi-Cal Certification").

60. During the relevant period, the Sleep Test Defendants derived revenue from the Medi-Cal program.

V. OVERVIEW OF PPS BUSINESS

61. PPS is a DME supplier. Its two main areas of business are: (1) home oxygen therapy (stationary and portable oxygen delivery equipment and supplies of oxygen, primarily to address chronic obstructive pulmonary disease in patients); and (2) sleep therapy (PAP devices, primarily to address obstructive sleep apnea in patients). PPS also supplies nebulized medication (nebulizer equipment and medication cups, which are also used to address chronic obstructive pulmonary disease).

62. According to the PPS website: "Today, PPS employs over 1000 associates. We serve communities from more than 100 local care centers across the United States. You'll find PPS in 20 states - California, Washington, Oregon, Nevada, Arizona, New Mexico, Colorado, Wyoming, Texas, Nebraska, Kansas, Oklahoma, Indiana, Illinois, Pennsylvania, Utah, Montana, Idaho, New Jersey, and Kentucky. …"

63. PPS organizes its sales efforts through Regions, Districts and Field Centers. Field Centers typically have a District Manager, an Operations Manager, Patient Care Coordinators ("PCCs"), Customer Service Representatives ("CSRs"), and Technicians. A District has multiple Field Centers within its area of sales, and a Region has multiple Districts.

64. The Region Director is responsible for developing, evaluating and implementing strategies to drive regional sales growth, and for recruiting and developing high-performing District Managers.

65. The District Manager is responsible for sales growth and operational execution of the Field Centers within the sales District. According to PPS training materials: "The DM supervises all aspects of operations, personnel, sales and service at his/her Centers." Further: "After the initial training of PCCs in the PPS on-boarding process, the District Manager has responsibility for ongoing training and coaching of the PCCs. The District Manager rides with the PCC on a regular basis to perfect sales techniques, share insights and role play as needed before sales calls."

66. The Patient Care Coordinators, according to PPS training materials, are the "key to our business." PPS employs approximately five PCCs in each of 100+ "care centers" in 20 States during the relevant period. "PCCs build relationships with Physicians, their office staff, and other Referral Sources (e.g. assisted living facilities, skilled nursing facilities, sleep labs/centers, etc., to earn the privilege of supporting their patients with quality home care services. PCCs also build relationships with patients directly through in-home visits. This gives PCCs the opportunity to be the Referral Source's 'eyes and ears' in the patient's home, bringing information back to them to ensure that patients receive the highest level of care."

67. The purpose of building these "relationships" and providing "information" to the "Referral Sources" is sales of PPS products and services. As stated in the PPS training materials: "The PCC position generates revenue for PPS by selling oxygen therapy, sleep therapy and respiratory medication products and services to Referral Sources. They do this by assisting Referral Sources with diagnosis and care of their patients. PCCs visit patients (both new and existing), gather non-clinical input, and report their observations and/or concerns (e.g. environmental or safety) to the key personnel at your Referral Sources."

68. PPS compelled its PCCs sell as many PPS products and services as they could through both minimum requirements and an incentive commission rewards scheme.

69. To remain employed, PCCs were required to convince physicians in their sales territory to prescribe a certain number of oxygen and PAP "set-ups" (meaning that a physician has filled out a "certificate of medical necessity" and/or prescription for PPS products and services). PPS Performance Standards for each of its PCCs were set as "green" ("Good Performance" with an average of 18 or more sales of new oxygen or sleep services monthly, or 54 or more quarterly), "yellow" ("Acceptable, Need to Improve" with an average of 15 to 17 sales of new oxygen or sleep services monthly, or 45 or more quarterly), or "red" ("Not Acceptable, Must Improve" with an average of 14 or less sales of new oxygen or sleep services monthly, or 42 or less quarterly). A PCC whose performance was "red" for three months is fired.

70. A typical CPAP "set-up" cost Medicare or Medi-Cal during the relevant period more than $1,235 per patient (per the DMEPOS Fee Schedule, the CPAP device alone, HCPCS E0601, cost $95 per month for a capped 13 month rental period). A typical BiPAP "set up" cost to Medicare or Medi-Cal during the relevant period was more than either $2,899 per patient (per

the DMEPOS Fee Schedule, HCPCS E0470, cost $223 per month for the capped 13 month rental period) or $7,553 per patient per the DMEPOS Fee Schedule, HCPCS E0471, cost $223 per month for the capped 13 month rental period). A typical stationary oxygen "set-up" cost Medicare or Medi-Cal during the relevant period more than $6,300 per patient (per the DMEPOS Fee Schedule, HCPCS E0424, cost $175 per month for the capped 36 month rental period). Moreover, each patient prescribed a CPAP, BiPAP or oxygen service had an ongoing need for replacement supplies with further significant cost to Medicare and/or Medi-Cal.

71. PCCs' initial base salary during the relevant period was about $40,000 per year. However, under the PPS compensation scheme, PCCs could greatly enhance their salary through the commissions they could earn by convincing physicians to prescribe new PPS oxygen and sleep services to their patients. PCCs only received commissions and salary increases (and avoided termination) by expanding PPS oxygen and sleep services to new patients, or selling new services to existing patients, thus creating an incentive for PCCs to continually increase the number of billings to the governments' health care programs.

72. Under the PPS Sales Commission Plan in the relevant period, a PCC could earn $100 per oxygen order for each new patient up to 23 new patients per quarter, $200 per oxygen order for each new patient from 24 to 44 new patients per quarter, and $400 per oxygen order for each new patient above 44 new patients per quarter. A PCC obtaining 50 new oxygen orders in a quarter would receive a commission of $8,900 for that quarter.

73. During 2009, 50 new oxygen orders would typically cost Medicare $315,000 over 36 months assuming each patient continued on oxygen for the allowed 36 months and that the rate of monthly reimbursement did not increase. Assuming that only 250 PPS PCCs nationwide sold 50 new oxygen orders in a single quarter, Medicare would pay out $78.75 million over 36

months assuming each patient continued on oxygen for the allowed 36 months and that the rate of monthly reimbursement did not increase.

74. Likewise, under the PPS Sales Commission Plan, a PCC could earn $100 per CPAP or BPAP order for each new patient up to 23 new patients per quarter, $150 per CPAP or BPAP order for each new patient from 24 to 44 new patients per quarter, and $300 per CPAP or BPAP order for each new patient above 44 new patients per quarter. A PCC obtaining 50 new CPAP or BPAP orders in a quarter would receive a commission of $7,250 for that quarter.

75. During 2009, 50 new CPAP orders would typically cost Medicare $61,750 over 13 months (plus supplies) assuming each patient continued on CPAP for the allowed 13 months and that the rate of monthly reimbursement did not increase. Assuming that only 250 PPS PCCs nationwide sold 50 new CPAP orders in a single quarter, Medicare would pay out $15.43 million over 13 months assuming each patient continued on CPAP for the allowed 13 months and that the rate of monthly reimbursement did not increase. If a single PCC had a quarter's sales of only 25 of the more expensive BPAP devices (E0471), such sales would cost Medicare $188,825 over 13 months (plus supplies) assuming each patient stayed on the BPAP for the allowed 13 months and the rate of reimbursement did not increase. Assuming that only 250 PPS PCCs nationwide sold 25 new, more expensive BPAP devices in a single quarter, Medicare would pay out $47.2 million over 13 months assuming each patient continued on that BPAP for the allowed 13 months and that the rate of monthly reimbursement did not increase.

76. High sales would also qualify a PCC for increased salary.

77. To qualify for the commission, however, the PPS Sales Commission Plan also required that PPS receive a minimum amount of money from the government and private insurance plans it billed. To qualify for a commission, stationary oxygen equipment and services

were required to generate at least $130/month in paid reimbursement to PPS. To qualify for a commission, sales of sleep products and services were required to include heated humidity (which created additional sales of PPS products) and the blower units were required to be reimbursed on a rental basis for a minimum of $500.

78. PCCs that generated high sales of PPS products and services to new patients also qualified for the PPS President's Club Program, which provided an opportunity for additional financial rewards. PPS also ran sales contests devised by Jason Anderson, Vice President of Sales. One such contest had PCCs earning "ping pong" balls for arranging for overnight pulse oximetry testing and for sales of PPS products and services. At the end of the contest, a certain number of ping pong balls would qualify the PCC for rewards, such as payment of the PCC's mortgage (up to $2000/month) paid for a year, a Rolex, or a doubling of salary for a quarter.

79. PPS District Managers, Customer Service Representatives ("CSRs"), and Technicians also were financially rewarded for sales of PPS products and services. All PPS employees had a financial interest in having physicians sign prescriptions and CMNs to new patients for oxygen, sleep therapy and neubulized medicine—and for the physician to refer the patients to PPS to provide those products and services.

80. Having motivated its PCCs by threat of termination for low sales and rich financial rewards for high sales, PPS trained its PCCs how to sell PPS products and services. The PPS training included lectures, written materials, role play videos, written exercises and tests. Sales tactics were described, observed and taught through "ride-alongs" with other PCCs and the District Managers, and in weekly sales meetings (in-person or by telephone) among each District's PCCs and the District Manager. The Regional Managers often would join the weekly sales meetings. Equally important, PPS encouraged new PPCs to emulate the sales tactics of

more senior, "successful" PCCs. As set forth below, many of these sales tactics were fraudulent, contrary to Medicare rules, and/or illegal.

81. The first step for all PCCs was to cultivate a close relationship with physicians and their staff who saw patients that might have a need for home oxygen therapy, sleep therapy, or nebulized medicine. PPS's goal was for its PCCs to develop such close relationships with physicians and their staff that the PCC becomes a *de facto* part of those physicians' offices. PPS rated each PCC's relationship with targeted physicians on a scale of 1 to 5 for the closeness of the relationship, with the lowest being a "professional visitor" and the highest being a "partnership seller."

82. To cultivate a close relationship, PCCs visited physicians' offices frequently, bringing small gifts such as coffee and pastries for the staff, and explaining PPS services to the staff. As the relationship developed, PCCs scheduled "in-service" luncheons, providing lunch to the physicians and staff, explaining PPS products and services, and selling such products and services as superior to other DME suppliers' products and services. The PCCs portrayed themselves to physicians' staff as experts on home oxygen treatment, sleep therapy, and nebulized medicine—and the Medicare and Medi-Cal rules regarding such services.

83. As set forth below in more detail, another key to PPS sales strategy was to get PPS PCCs into patients' homes so that they could gather information about the patients and their living conditions, and then approach physicians to seek further testing or PPS products for such patients. PPS PCCs aggressively sought to ensure that every patient receiving PPS sleep therapy products was also prescribed PPS home oxygen services.

84. Alcaine began working at PPS on March 2, 2009 and was terminated on January 27, 2010. He was hired and worked as a PCC out of PPS' San Leandro, California office. His

immediate supervisor was Karen Vickrey, the District Manager. The Regional Manager overseeing his District originally was Pete Flath and later Deena Meyers. The Vice-President-Sales was Jason Anderson.

85. PPS trained Alcaine through lectures, written materials, role play videos, written exercises and tests, and field "ride-alongs." Although PPS written materials often discussed compliance with Medicare and Medicaid laws and program instructions, PPS taught its PCCs how to "sell" PPS products through "ride-alongs" and sales meetings that endorsed tactics and techniques that violated such laws and program instructions.

86. District Manager Karen Vickrey encouraged Alcaine and other PCCs to emulate the sales tactics of more senior, successful PCCs. Alcaine was taught sales tactics through "ride-alongs" with other PCCs and the District Manager, "role play" with the District Manager and other PCCs, and in weekly sales meetings (in-person or by telephone) among the District's PCCs and the District Manager. The Regional Manager often would join the weekly sales meetings.

87. Alcaine initially was given sales responsibility for Castro Valley and the City of Alameda, which included two hospitals and about 50 potentially relevant physicians. Alcaine visited other sales territories with other PCCs during "ride-alongs" and when other PCCs needed help with coverage. Alcaine observed PCCs' sales tactics and conduct during such "ride-alongs," and was informed of other PCCs' sales methods both to cover their territories when needed and through discussions of successful sales tactics in weekly sales meetings.

88. Upon information and belief, PPS has trained its PCCs to engage in similar sales tactics and conduct in all of 20 States in which it operates (California, Washington, Oregon, Nevada, Arizona, New Mexico, Colorado, Wyoming, Texas, Nebraska, Kansas, Oklahoma, Indiana, Illinois, Pennsylvania, Utah, Montana, Idaho, New Jersey, and Kentucky).

89. A significant majority of the patients to which PPS sold oxygen equipment and supplies, and PAP devices and supplies, were (and are) Medicare patients. As stated in PPS training materials: "Medicare is the largest provider of insurance in the United States and the dominant payer for PPS oxygen service." PPS also served (and serves) many Medi-Cal patients as well as patients billing TRICARE. As stated in PPS training materials: "PPS does serve a significant number of Medicaid/Medi-Cal patients." PPS billed Medicare and Medi-Cal for such equipment and supplies.

VI. KICKBACKS AND FRAUD IN THE SLEEP THERAPY BUSINESS

A. Medicare Rules Regarding PAP Devices and Service

90. During the period of Alcaine's employment and to the present, PPS sales of sleep therapy products and services to patients in California for which PPS sought reimbursement under the Medicare program were subject to CMS Publication 100-03, the Medicare National Coverage Determination Manual, Coverage Determinations, Chapter 1, Part 4, Section 240.4 Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (Rev. 96, 10-15-08) (the "PAP NCD") and CMS Publication 100-03, the Medicare National Coverage Determination Manual, Coverage Determinations, Chapter 1, Part 4, Section 240.4.1 – Sleep Testing for Obstructive Sleep Apnea (OSA) (Rev. 103, Effective March 3, 2009) ("Sleep Testing NCD").

91. The requirements of the PAP NCD and the Sleep Testing NCD were incorporated into the Local Coverage Determination ("LCD") for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L171), issued by Noridian Administrative Services and effective for services rendered after January 1, 2009 (the "2009 PAP LCD"). A revised LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea

(L171) was issued by Noridian Administrative Services effective for services rendered after April 1, 2010, which in all aspects material to the claims herein is the same as the 2009 PAP LCD. As Alcaine was terminated before the 2010 PAP LCD was effective, references herein are to the 2009 PAP LCD.

92. The 2009 PAP LCD sets forth the requirements for Medicare to cover a PAP device:

> Coverage of a PAP device for the treatment of OSA is limited to claims where the diagnosis of OSA is based upon a Medicare-covered sleep test (Type I, II, III, or IV. A Medicare-covered sleep test must be either a polysomnogram performed in a facility-based laboratory (Type I study) or a home sleep test (HST) (Types II, III, or IV). The test must be ordered by the beneficiary's treating physician and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

B. PPS and Sleep Test Defendants Fraudulent Kickbacks Regarding Sleep Therapy

93. During the relevant period, PPS' PCCs repeatedly and routinely engaged in sales practices for PPS sleep therapy products that defrauded the federal Medicare and Medicaid programs and California's Medi-Cal program. In violation of the AKS, PCCs, as directed and taught by PPS and with the knowing consent of PPS managers, knowingly engaged in kickback arrangements with the Sleep Test Defendants to provide referrals of patients for sleep testing in exchange for Sleep Test Defendant-associated physicians providing or recommending prescriptions for PPS PAP devices.

94. PPS had and has a division named "Peak Sleep," which provides services related to sleep therapy. Many of PPS' sleep therapy patients received equipment and services paid for by federal health care programs or the Medi-Cal program.

95. PPS PCCs attempted to develop close relationships with physicians, hospitals and clinics that were in a position to refer patients to sleep testing for OSA and then to PPS for PPS sleep therapy products. At PPS' direction and with PPS' knowledge and consent, during visits to physicians' offices, PCCs spoke to patients about the benefits of sleep therapy and recommended that the patients ask the physician about being tested for OSA. PCCs also spoke to physicians and their staff about patients that the PCCs had talked to, either in the waiting rooms or at home during deliveries of oxygen equipment, about difficulties sleeping. PCCs recommended to the physician and/or staff that such patients undergo sleep testing to determine whether they had OSA and needed sleep therapy devices.

96. At the request of PPS PCCs, physicians often would sign prescriptions for PSG sleep testing prepared by PPS on either a PPS prescription form or on the form of a PPS-favored sleep test facility.

97. PPS focused its sales strategy on trading its facilitation of sleep testing referrals to sleep clinics in exchange for sleep clinic physicians providing or recommending prescriptions for PPS sleep therapy products.

98. In training materials, PPS explained the referral process to its PCCs as follows:

> The referral process for a sleep patient may involve several entities, including but not limited to a Primary Care Physician/Family Practitioner, a Specialist such as a Pulmonologist or Internist, and a Sleep clinic. You must fully understand how the referral process works in each account and know who is responsible for writing the prescriptions.

Generally, someone will visit their Primary Care Physician (PCP), usually a Family Practitioner or Internist, complaining of symptoms. If aware of possible Obstructive Sleep Apnea (OSA), the PCP will refer the patient to either a Pulmonologist who will then, will turn, refer the patient to a sleep clinic, or the PCP will refer the patient directly to the sleep clinic.

For discussion purposes, let's use the example of a patient being referred directly to a sleep clinic by a PCP. The PCP writes a prescription for a sleep study to be performed at a sleep clinic. Once the study is done, and if the patient is diagnosed with OSA, the sleep clinic or the PCP writes the Rx for CPAP therapy.

99. As set forth below, PPS viewed the multiple referrals as an opportunity for it to offer patient referrals as an inducement for prescriptions.

100. Under the AKS, DME suppliers may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend DME equipment or services that may be paid for by a federal health care program. Similarly, under the AKS, physicians or clinics providing sleep testing services may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce a DME supplier or others to recommend that such physicians or clinics perform sleep testing that may be paid for by a federal health care program.

101. Also, under the AKS, DME suppliers may not knowingly and willfully solicit or receive any remuneration, including prescriptions for sleep therapy equipment and service, directly or indirectly, in return for referring patients or recommending that physicians refer patients to physicians or clinics to perform sleep testing that may be paid for by a federal health care program. Similarly, under the AKS, physicians or clinics providing sleep testing services

may not solicit or receive any remuneration, including patient referrals or recommendations to refer patients, directly or indirectly, in return for prescribing a DME supplier's sleep therapy equipment and service that may be paid for by a federal health care program.

102. Notwithstanding the clear mandates of the AKS, PPS management directed and encouraged its PCCs to enter into reciprocal referral arrangements with sleep testing clinics. PPS training materials explained how PCCs could use their ties to physicians to generate sleep testing referrals that in turn could be used to get prescriptions from sleep clinic physicians:

Intermediate the Referral Process

The PCP

Understanding each account's referral process creates opportunities for you. Get to know which PCPs need help with the process. Offer to help them find a lab that has openings for when they have a patient they want to quickly get in for a study. Offer to handle the patient from beginning (coordinate the sleep study) to end (CPAP set-up and post set-up care).

The Sleep Clinic

Ask the clinic whether they will give you the CPAP business if you bring them a patient and if OSA is diagnosed. If a PCP trusts you enough to help her office find the right sleep clinic, and coordinate the sleep study, then you can bring business to that sleep clinic. This intermediation of the referral process can help you determine which clinics get patients and help make sure that you get the Rx for sleep therapy when the time comes. If you are able to bring the clinic patients, it makes sense that they will use you for the DME when appropriate. (Emphasis added).

103. PPS showed its PCCs a training video where two District Managers played PCCs and a PPS Vice-President of Sales played a sleep clinic director. The video showed the PPS PCCs proposing an arrangement where PPS brought patients to the sleep clinic for sleep testing in exchange for the sleep clinic physicians writing prescriptions for PPS sleep therapy products.

104. PPS PCCs followed the directions provided by PPS management and entered into explicit arrangements with sleep testing facilities to trade referrals for prescriptions.

105. Defendant San Leandro Sleep Disorders Center ("SLSDC") was located in San Leandro, California. Many of the physicians who owned SLSDC referred their own Medicare and Medi-Cal patients to the SLSDC for sleep testing.

106. PPS PCC Kelly Guerrero had an arrangement with Kevin Angelo, the Clinical Coordinator of the SLSDC to "keep the beds full" at SLSDC by referring patients to SLSDC for PSG sleep tests in exchange for SLSDC physicians, primarily Dr. R.S. Rajah and Dr. Paul Robinson, writing prescriptions for such patients to receive PPS PAP equipment and supplies. While many sleep centers recommended a variety of ways to address OSA, SLSDC consistently recommended and prescribed CPAP with PPS equipment.

107. PPS PCC Chris Garrity had an arrangement with Defendants Dr. Kirit B. Patel, Dr. Jagjeet Kalra and Dr. Ron Kass, doing business as Hayward EB Sleep Disorders Medical Center in Hayward, CA to trade two referrals of patients to the Hayward EB Sleep Disorders Medical Center for PSG sleep tests in exchange for one prescription by Hayward EB Sleep Disorders Medical Center-associated physicians for a patient to receive PPS PAP equipment and supplies.

108. PPS PCC Lydia Carson in Martinez had a deal with the Contra Costa Sleep Center in Walnut Creek to trade one referral of patients to the Contra Costa Sleep Center for a

PSG sleep study in exchange for one prescription by Contra Costa Sleep Center-associated physicians for a patient to receive PPS PAP equipment and supplies, as long as she helped them to maintain the number of beds in the center booked for testing.

109. PPS PCCs Rebecca Liebert and Alicia Pierce had deals with Dr. Man Kong Leung, operating as Pacific Coast Sleep Disorders in Pleasanton, CA and Dr. Haramandeep Singh, operating as Sleep Medicine Specialists of California in San Ramon, to refer as many patients to them as they could for PSG sleep tests in exchange for the physicians writing prescriptions for such patients to receive PPS PAP equipment and supplies.

110. In entering into these arrangements, both PPS and the Sleep Test Defendants knowingly entered into illegal kickback arrangements that violated the Anti-Kickback Statute, and violated their Certifications that they would comply with the AKS.

C. SLSDC Fraudulent Claims for Continued PAP Coverage

111. For a Medicare patient to continue receive Medicare coverage of a PAP device beyond the first three months of therapy, the 2009 PAP LCD requires that certain criteria be met:

> Continued coverage of a PAP device (E0470 or E0601) beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating physician must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy.
>
> For PAP devices with initial dates of service on or after November 1, 2008, documentation of clinical benefit is demonstrated by:
>
> 1. Face-to-face clinical re-evaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; and,

2. Objective evidence of adherence to use of the PAP device reviewed by the treating physician. . . .

If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not medically necessary.

112. During the relevant period, the SLSDC Clinical Director, Kevin Angelo, was not a licensed physician. He was not the "treating physician" for Medicare patients that underwent PSG sleep testing at the SLSDC and who were prescribed PAP devices by SLSDC-affiliated physicians. Mr. Angelo required PPS to provide him data on PAP device usage by such Medicare patients as part of the re-evaluation for such patients required by the 2009 PAP LCD. PPS did so by, among other things, directing its PCCs to visit such patients and collect the memory cards from their PAP devices. Mr. Angelo also met with such patients at the SLSDC without a physician present.

113. Upon information and belief, SLSDC-associated physicians, including Dr. RS Rajah and Dr. Paul Robinson, billed Medicare for a "face-to-face clinical re-evaluation by the treating physician" of such patients when Mr. Angelo, and not themselves, met with such patients to evaluate them. Such claims were false and fraudulent. Further, such physicians continued prescription of PAP devices for such patients without conducting the "face-to-face clinical re-evaluation by the treating physician" required by the 2009 PAP LCD. By such conduct, such physicians caused false and fraudulent claims to be submitted to Medicare for continued coverage, and violated their Medicare Certifications.

VII. FRAUD IN THE PPS HOME OXYGEN BUSINESS

A. Medicare Rules Regarding Oxygen Equipment and Supplies

114. As shown below, PPS enhanced its profits at the expense of the federal and California health care programs by falsifying test results to qualify patients for home oxygen service. In addition, PPS consistently violated Medicare program instructions governing the home oxygen business by corrupting why and how pulse oximetry tests were performed on and reported about Medicare patients to qualify them for home oxygen service.

115. During the period of Alcaine's employment and to the present, PPS sales of home oxygen products and supplies to patients in California for which PPS sought reimbursement under the Medicare program were subject to CMS Publication 100-03, the Medicare National Coverage Determination Manual, Coverage Determinations, Chapter 1, Part 4, Section 240.2 (Rev. 1, 10-03-03, CIM 60-4) (the "Oxygen NCD"). The requirements of the Oxygen NCD were based upon, and reinforced by, the Medicare Coverage Issues Manual, CMS Publication 100-06, Part 60-4.

116. The Oxygen NCD provides: "Medicare coverage of home oxygen and oxygen equipment under the durable medical equipment (DME) benefit (see §1861(s)(6) of the Act) is considered reasonable and necessary only for patients with significant hypoxemia who meet the medical documentation, laboratory evidence, and health conditions specified in subsections B, C, and D." "A physician's certification of medical necessity for oxygen equipment must include the results of specific testing before coverage can be determined."

117. The Oxygen NCD specifically addresses the laboratory evidence necessary to warrant home oxygen and oxygen equipment. "Initial claims for oxygen therapy must also include the results of a blood gas study that has been ordered and evaluated by the attending physician. This is usually in the form of a measurement of the partial pressure of oxygen (PO2) in arterial blood. A measurement of arterial oxygen saturation obtained by ear or pulse oximetry,

however, is also acceptable when ordered and evaluated by the attending and performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services. ... A DME supplier is not considered a qualified provider or supplier of laboratory services for purposes of these guidelines. ... The conditions under which the laboratory tests are performed must be specified in writing and submitted with the initial claim, i.e., at rest, during exercise, or during sleep." (Emphasis added).

118. The Oxygen NCD describes three different types of pulse oximetry testing, and the type of oxygen service that is authorized depending upon the identified arterial oxygen saturation. One oximetry test is taken while the patient is "at rest, breathing room air," and was referred to by PPS as either the "At-Rest" test or "Spot Check." Another oximetry test consists of three separate measurements, including a measurement when the patient is exercising, and was referred to by PPS as either the "Activities of Daily Living" test or the "At-Exercise" test. The third type of oximetry testing was an overnight test while the patient is asleep and was referred to by PPS as an "At-Sleep" test or "overnight pulse oximetry study." At Rest and At Exercise tests are performed only at a physician's office, a hospital or at an Independent Diagnostic Testing Facility (IDTF). An At-Sleep Test can be done at home.

119. In 2005, CMS issued a One-Time Notification, Transmittal 173, CMS Publication 100-20, regarding Overnight Oximetry Testing ("Transmittal 173"). Transmittal 173 provided explicit "guidance on when a DME supplier may deliver test equipment on behalf of a Medicare-enrolled Independent Diagnostic Test Facility (IDTF)." Transmittal 173 provides:

> Beneficiaries may self administer home based overnight oximetry tests under the direction of a Medicare enrolled Independent Diagnostic Testing Facility (IDTF). Further, a DME supplier or another shipping entity may deliver a pulse oximetry test unit

and related technology used to collect and transmit test results to the IDTF to a beneficiary's home under the following circumstances:

1) The beneficiary's treating physician has ordered an overnight pulse oximetry test.

2) The test is performed under the direction and/or instruction of a Medicare-approved IDTF. Because it is the beneficiary who self-administers this test, the IDTF must provide clear written instructions to the beneficiary on proper operation of the test equipment and must include access to the IDTF in order to address other concerns which may arise. Because CMS Pub.100-3, section 240.2.C prohibits DME suppliers from performing tests, the DME supplier may not create this instruction nor participate in the conduct of the test.

3) The test unit is sealed and tamper-proof such that test results cannot be accessed by anyone other than the IDTF who is responsible for transmitting a test report to the treating physician. The DME supplier may use related technology to download test results from the testing unit and transmit those results to the IDTF. In no cases may the DME supplier access or manipulate the test results in any form.

120. Transmittal 173 concluded: "Because the DME supplier cannot access the test results, and is acting merely as a courier of equipment, and is not involved in instructing the beneficiary how to perform the test, this does not violate the prohibition found in CMS Pub.100-3, Section 240.2.C 'A DME supplier is not considered a qualified provider or supplier of laboratory services for purposes of these guidelines.'"

121. The requirements of the Oxygen NCD and Transmittal 173 were incorporated into the Local Coverage Determination ("LCD") for Oxygen and Oxygen Equipment (L11457), issued by Noridian Administrative Services and effective for services rendered after January 1, 2009 (the "2009 Oxygen LCD"). A revised LCD for Oxygen and Oxygen Equipment was issued by Noridian Administrative Services effective for services rendered after January 1, 2010 (the "2010 Oxygen LCD"). In all aspects material to the claims in this Complaint,, the 2010 Oxygen LCD was the same as the 2009 Oxygen LCD. As the 2009 Oxygen LCD was applicable during most of the period of Alcaine's employment, this Complaint references the 2009 Oxygen LCD.

122. Under the 2009 Oxygen LCD:

> Home oxygen therapy is covered only if all of the following conditions are met:
>
> 1. The treating physician has determined that the patient has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy, and
>
> 2. The patient's blood gas study meets the criteria stated below, and
>
> 3. The qualifying blood gas study was performed by a physician or by a qualified provider or supplier of laboratory services, and
>
> 4. The qualifying blood gas study was obtained under [specified] conditions: … and
>
> 5. Alternative treatment measures have been tried or considered and deemed clinically ineffective.

123. As stated in the 2009 Oxygen LCD: "The qualifying blood gas study must be one that complies with the Fiscal Intermediary or Local Carrier policy on the standards for conducting the test and is covered under Medicare Part A or Part B. This includes a requirement

that the test be performed by a provider who is qualified to bill Medicare for the test – i.e., a Part A provider, a laboratory, an Independent Diagnostic Testing Facility (IDTF), or a physician. A supplier is not considered a qualified provider or a qualified laboratory for purposes of this policy. Blood gas studies performed by a supplier are not acceptable. In addition, the qualifying blood gas study may not be paid for by any supplier. This prohibition does not extend to blood gas studies performed by a hospital certified to do such tests."

124. Consistent with Transmittal 173, the 2009 Oxygen LCD set limits on a DME supplier's involvement in home-based overnight pulse oximetry testing:

> Beneficiaries may self-administer home based overnight oximetry tests under the direction of a Medicare-enrolled Independent Diagnostic Testing Facility (IDTF). A DME supplier or another shipping entity may deliver a pulse oximetry test unit and related technology, used to collect and transmit test results to the IDTF, to a beneficiary's home under the following circumstances:
>
> 1. The beneficiary's treating physician has contacted the IDTF to order an overnight pulse oximetry test before the test is performed.
>
> 2. The test is performed under the direction and/or instruction of a Medicare-approved IDTF. Because it is the beneficiary who self-administers this test, the IDTF must provide clear written instructions to the beneficiary on proper operation of the test equipment and must include access to the IDTF in order to address other concerns that may arise. The DME supplier may not create this written instruction, provide verbal instructions, answer questions from the beneficiary, apply or demonstrate

the application of the testing equipment to the beneficiary, or otherwise participate in the conduct of the test.

3. The test unit is sealed and tamper-proof such that test results cannot be accessed by anyone other than the IDTF who is responsible for transmitting a test report to the treating physician. The DME supplier may use related technology to download test results from the testing unit and transmit those results to the IDTF. In no cases may the DME supplier access or manipulate the test results in any form.

The IDTF must send the test results to the physician. The IDTF may send the test results to the supplier if the supplier is currently providing or has an order to provide oxygen or other respiratory services to the beneficiary or if the beneficiary has signed a release permitting the supplier to receive the report. (Emphasis added).

125. In December 2006, Noridian published "Oximetry Testing FAQs" to further explain the rules to DME oxygen suppliers. Several FAQs are pertinent here:

Q1. The June 2006 Bulletin states that for an oximetry test to serve as a "qualifying test," the Beneficiary's treating physician must have contacted the IDTF to order an overnight pulse oximetry test before the test is performed. If the supplier receives, a written order for oximetry from the physician, can the supplier forward the order to the IDTF?

A1. The physician must order the oximetry test prior to the test being performed. If the physician forwards the order to the supplier, the supplier may forward the order to the lab. The IDTF must have a written order in its file prior to performing any testing.

Q2. The June 2006 Bulletin states "Suppliers are cautioned that sleep oximetry testing must be based on a request that is initiated by the treating physician. It is inappropriate for a supplier or IDTF to initiate a contact with the physician either directly or through the beneficiary to request, suggest or otherwise seek an order for an oximetry test." Are there any circumstances where a supplier could contact a patient or a physician about the need to obtain an oximetry test?

A2. Suppliers are reminded that only a physician may order an oximetry test. However, a supplier would be permitted to contact the physician or the beneficiary about the need to obtain an oximetry test under the following [inapplicable] circumstances . . .

126. The Noridian DME MAC Jurisdiction D Supplier Manual, Chapter 4, "Evidence of Medical Necessity for Oxygen CMN," clearly explains why Medicare rules forbid DME suppliers from conducting oximetry tests used to qualify Medicare patients for home oxygen: "Qualifying tests must be conducted by the treating physician or a provider certified to conduct such tests. Because of the potential for conflict of interest, the results of oximetry tests conducted by a DME supplier cannot be accepted to establish the need for home oxygen therapy services, either in initial claims or when accompanying recertification CMNs."

127. DME suppliers may not solicit oximetry tests, perform such tests, fund such tests, provide such tests for free, select the IDTFs to perform such tests, access test results other than from the physician-selected IDTF, or instruct patients how to perform such tests. The purpose of these Medicare program instructions is to strictly limit the involvement of DME suppliers in

determining whether oxygen therapy is medically necessary because of the suppliers' obvious monetary interest having the patient use oxygen regardless of circumstance or need.

B. PPS' Fraudulent Conduct Regarding Oxygen Equipment and Service

128. During the relevant period and despite the applicable Medicare program instructions, PPS' PCCs repeatedly and routinely engaged in sales practices for PPS oxygen products that defrauded federal and California health care programs. As set forth below, PCCs, as taught by PPS and with the knowing consent of PPS managers, knowingly falsified information relied upon in physicians' prescriptions and CMNs for PPS oxygen products, knowingly provided free use of PPS oximeters to physicians to induce them to prescribe PPS oxygen products for Medicare and Medi-Cal patients, and knowingly violated Medicare program instructions to sell oxygen product despite PPS' certification that its employees would not do so.

- **PPS Falsified At-Rest Oximetry Test Results**

129. During the relevant period, at PPS' direction and with PPS' knowledge and consent, PPS PCCs on many occasions, falsified pulse oximetry testing results to qualify patients for oxygen therapy under the Medicare rules. One method of doing so was to exercise a patient before performing an "At Rest" pulse oximetry test. In so doing, the patient's blood is desaturated – the oxygen levels go down -- even though the At-Rest test is meant to measure arterial oxygen saturation when a patient is at rest. Immediately after the PCC exercised the patient, either the PCC or physician's staff conducted a pulse oximetry test that was reported in the patient's medical file as an "At-Rest" test. The patient's oxygen level, pushed to artificially low levels because of the physical activity, would then qualify for oxygen equipment and supplies under the alleged "At Rest" test.

130. Among others during the relevant time period, PPS PCC Kristel Rochios engaged in such conduct in the offices of Dr. Norman Banks at the Brookside Community Health Center in San Pablo, CA and Dr. Hsu Hwei Jung in San Pablo, CA, and at the West Berkeley Family Practice in Berkeley, California and at the Elmwood Care Center in Berkeley, California. PCC Lydia Carson engaged in such conduct with patients of the Contra Costa Regional Medical Center, both at the Center and in the patients' homes. PCC Rebecca Leibert engaged in such conduct on patients of Dr. Richard Oliver of the Chabot Nephrology Medical Group in Pleasanton, CA. PCC Amber Davis also engaged in such conduct. PCC Chris Garrity also engaged in such conduct, including for patients of Dr. Deepti Saxena in Fremont, CA. PCC Kelly Guerrero engaged in such conduct with patients at the Eastmount Clinic in Oakland, CA and with patients of the Centers for Elder Independence ("CEI"). District Manager Karen Vickrey was aware of and encouraged such conduct. It was common among PPS PCCs.

131. PPS PCCs used the reported "At-Rest" pulse oximetry results in preparing prescriptions for PPS oxygen equipment and supplies on PPS forms, which were then given to physicians for review and signature. After a physician signed the prescription, the prescription was given to a PPS Customer Service Representative (CSR) to prepare a Certificate of Medical Necessity for Oxygen for physician review, completion and signature. Physicians relied upon the reported At-Rest pulse oximetry test results as the necessary laboratory evidence to qualify a Medicare or Medi-Cal patient for PPS home oxygen. PPS knowingly submitted CMNs relying on the falsely reported At-Rest pulse oximetry test results to the Medicare and Medi-Cal programs to request payment for oxygen equipment provided to Medicare and Medi-Cal patients.

132. Such conduct violated the 2009 Oxygen LCD, the Oxygen NCD, and the Medi-Cal criteria in Durable Medical Equipment (DME): Bill for Oxygen and Respiratory Equipment,